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July 24, 2003

Ms. Laura Shay
Food & Drug Administration
HFD 560
9201 Corporate Boulevard
Rockville, MD 20850
301-827-2274

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Laura,

We are submitting to you another copy of our "Time and Extent Application" (TEA) for Amiloxate, (INCI, Isoamyl Methoxycinnamate) our product Neo Heliopan® E-1000.

We have gone through this copy and marked ("high lited") the passages and portions that we deem "Confidential". I am also including an outline of what was done to help you with the task. (THIS IS THE ONLY COPY!!!)

Deemed Confidential:

Section 1.

- Page 1. Method of Synthesis paragraph 1.
- Page 2. The confidential paragraph in §330.14(c) (2) and the 12,100-kg shown in the table.
- Page 3. The table showing the amount sold per year in Australia.
- Page 4. All of this.
- Page 5. The table.
- Page 6. The table.
- Page 9. § 330 (c) (3) Last sentence of the text as well as the individual country details which continues on page 10.
- Page 10. § 330.14 (c) (8) Keep the first sentence, the rest is confidential.

Section 1. Every page except the last one which is a copy of the CTFA Dictionary listing for E 1000. I do not believe that our competitors should see our specs, C of A and analytical methods.

Sections 6, 9, 12 and 13. All of these.

Please contact me if anything is unclear to you and we hope that FDA agrees with our assessment of the portions that are and should be held as confidential.

Sincerely,

Karl A. Harris
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North America, Cosmetic Division
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